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Published in:
Netherlands Journal of Medicine

Publication date:
2005

Netherlands
The Journal of Medicine

Shared care with task delegation to nurses for type 2 diabetes: prospective observational study

L.J. Ubink-Veltmaat[1,2*], H.J.G. Bilo[2], K.H. Groenier[1], R.O. Rischen[3], B. Meyboom-de Jong[1]

[1]Department of Family Practice, University of Groningen, Groningen, the Netherlands, [2]Isala Clinics, Diabetes Outpatient Clinic, Zwolle, the Netherlands, tel.: +31 (0)38-424 25 18, fax:+31 (0)38-424 33 67, e-mail: l.j.veltmaat@isala.nl, [3]'t Veen Family Practice, Hattem, the Netherlands, *corresponding author

ABSTRACT

Background: To study the effects of two different structured shared care interventions, tailored to local needs and resources, in an unselected patient population with type 2 diabetes mellitus.

Methods: A three-year prospective observational study of two interventions and standard care. The interventions involved extensive (A) or limited (B) task delegation from general practitioners to hospital-liaised nurses specialised in diabetes and included a diabetes register, structured recall, facilitated generalist-specialist communication, audit and feedback, patient-specific reminders, and emphasised patient education. The target population consisted of 2660 patients with type 2 diabetes treated in the primary care setting. Patients who were terminally ill or who had been diagnosed with dementia were excluded from the study.

Results: The participation rates were high (90%) for patients, and none of the 64 GPs discontinued their participation in the study. Longitudinal analyses showed significant improvements in quality indicators for both intervention groups (process parameters and achieved target values on the individual patient level); in standard care, performance remained stable or deteriorated. Both patients and caregivers appeared satisfied with the project.

Conclusion: This study shows that structured shared care with task delegation to nurses, targeted at a large unselected general practice population, is feasible and can positively affect the quality of care for patients with type 2 diabetes.

INTRODUCTION

Type 2 diabetes mellitus (type 2 DM) is a chronic disease, which leads to considerable morbidity and premature mortality.[1,2] The prevalence of type 2 DM is high and is increasing.[3] Since most patients with diabetes die from complications of atherosclerosis, they should receive intensive preventive interventions to reduce their cardiovascular risk.[4] Guidelines for clinical practice have been developed in many countries to optimise diabetes care.[5,6] However, the implementation of these guidelines has not been straightforward.[7,8] There are many reasons for this, including a lack of time, recall facilities and diabetes registers, staffing problems, poor quality of documentation, the unavailability of qualified nurses, problems with patient compliance, inadequate reimbursement, lack of physician consultative assistance, and long waiting lists for ophthalmologists.[9,10]

As in other countries, in the Netherlands the care for type 2 DM patients is concentrated in the primary care setting,[6,11] and there is a growing shortage of primary healthcare providers.[12,13]

Structured shared care can partially resolve the aforementioned problems and may also improve the quality of care for patients with diabetes.[14] Multifaceted complex interventions which target different barriers preventing change are the most effective. Successful interventions include applying organisational strategies that increase structured recall, protecting time which has been reserved for diabetes care, using multifaceted professional interventions, facilitating generalist-specialist communication, delegating tasks to practice assistants or nurses and using specialist diabetes nurse facilitators. Nurses can play an important role in encouraging compliance and educating

patients. In certain situations, they can even replace physicians in delivering many aspects of diabetes care.[9,10,14-16]

Previous studies on diabetes care in general practice have tended to include highly selected populations of practitioners and patients.

Our aim was to study the effects of two different forms of structured shared care, tailored to local needs and resources, and of standard care in an unselected type 2 DM patient population in a prospective observational study.

MATERIALS AND METHODS

Study design

The Zwolle Outpatient Diabetes project Integrating Available Care (ZODIAC) study investigated the effects of a shared care project for type 2 DM. In the Netherlands, general practitioners (GPs) collaborate in GP working groups. A GP working group consists of several GPs who practice in the same area or town, and cover for each other in the delivery of medical services during out-of-office hours. Eight GP working groups (64 GPs) in the east of the Netherlands agreed to participate in the study. Three GPs were excluded from the study, two because they had recently started a new practice and one due to retirement. For pragmatic reasons, allocation to the two intervention groups and to the standard care group was assigned according to the preference of the GP working groups as a whole. As Greenhalgh mentioned, it is important to recognise that the different ways in which GPs organise their diabetes care and in which they interface with specialist services is a function of both the particular needs of their practice populations and their individual skills and confidence.[14] Moreover, for interventions to work, the methods must be acceptable to the target groups.[17]

The 32 GPs who participated in intervention A received extensive support from nurses specialised in diabetes (DSNs) who were hospital based, but who worked for the project in the primary care setting. The second group (intervention B, 21 GPs) received limited support from DSNs, and the third group (intervention C, 8 GPs), the standard care group, delivered standard care and received no extra support. In this project, 1.6 full-time equivalent DSNs were employed.

INTERVENTIONS

Extensive support (intervention A) means that DSNs, rather than the GPs, performed the annual examination according to the national guidelines of the Dutch College of General Practitioners for all the DM patients treated in the primary healthcare setting. The GPs remained responsible for the check-ups that should take place every three months. On top of this, the DSNs gave one-on-one education, tailored to the needs of the individual patients. Fundus photography[18] was integrated into the consultation as well, where normally each patient would have been referred to an ophthalmologist. If necessary (according to retinal photography results, or in the case of a newly diagnosed diabetes) a referral to the ophthalmologist was arranged by the DSN. The appointments with the DSNs took place outside the hospital in the primary healthcare setting in the village or city where the patient lived. Any patient who missed his or her appointment was rescheduled. Patients who were housebound with serious comorbidity were visited at home. A comprehensive structured report of the results was sent to the GP within three weeks.

If necessary, the results were accompanied by recommendations from the DSN concerning referrals to a dietician, chiropodist, and/or podiatrist, and by a recommendation from an internist concerning treatment (according to the guidelines). This process allowed the GPs to dedicate their consultation time to discussing the results with the patient in detail, and to decide how to act upon them. The GPs kept the full responsibility for the care of the patients and were not under any obligation to follow the recommendations they were given. A second part of the extensive support structure was the possibility of sending individual patients directly to the DSN for an on-demand consultation within the primary healthcare setting (without, as in standard care, a formal referral to secondary care). Possible reasons for requesting such a consultation could be for patient education, instruction on self-monitoring, or instruction on insulin injection. The GPs were responsible for determining the initial insulin dosages and for making any dosage changes.

The only extraneous support the GPs in intervention group B received was having direct access to on-demand consultations with the DSN, without the need for a formal referral to secondary care. They performed the annual and three-monthly check-ups themselves, including making any necessary referrals to the ophthalmologist.

In the standard care group (8 GPs), patient care was delivered as usual, with no extra support. Consultation with a DSN was only possible through a formal referral to the internist in the secondary healthcare setting.

All participating GPs received one-time feedback about their baseline performance, which was discussed within the GP working group in the presence of an internist.

Patients

The target population consisted of patients with type 2 diabetes who were being treated in the primary care setting, and the aim was to have an unselected population. Virtually all citizens of the Netherlands are registered with a GP. Annually, the GPs provided lists with the

names of all the patients who were known to have type 2 diabetes, as defined by the guidelines of the Dutch College of General Practitioners.[6] Patients with type 1 diabetes were excluded. Type 1 diabetes was defined by age at diagnosis <40 years and a requirement for insulin within one month of diagnosis. A total of 155,774 persons were registered with the 61 participating GPs, 3362 of whom had been diagnosed with type 2 diabetes mellitus. Patients were only excluded if they were being treated in secondary care by an internist, if they were terminally ill, or if they had been diagnosed with severe dementia.

Data collection

We collected data on all the eligible patients with type 2 DM who were registered with and were treated by the 61 GPs, during the three consecutive years from 1998 to 2000. The data were collected annually for all patients from the (electronic and/or paper) patient records in the general practice (including correspondence with specialists) by the principal investigator of the study. Additionally, data were collected by the investigator from the reports on the consultations by the DSNs in the intervention groups A and B.

The data were collected on full medical history, microvascular and macrovascular complications, diabetes and other medication(s), referrals for ophthalmological examination, measurements of blood pressure and weight, foot examination, smoking status, and laboratory measurements: HbA_{1c}, total cholesterol, HDL cholesterol, triglycerides, creatinine, microalbuminuria, and albumin-creatinine ratio in urine (reference value for HbA_{1c} 4.0 to 6.0%). The blood pressure was measured by the DSN in intervention group A, and by the GP in intervention group B and in the standard care group. The blood pressure was measured twice with a Welch Allyn Sphygmomanometer in the supine position after at least five minutes of rest. Renal clearance was calculated by the Cockroft and Gault formula.[19] The data on patient and provider satisfaction were collected by asking the GP 'How do you judge the shared care project?' and 'How do your patients judge the shared care project?' The Medical Ethics Committee of the Isala Clinics (formerly Weezenlanden Hospital) approved this study.

Outcome measurements

The effects of the interventions were measured by changes in three quality indicators. We studied (1) process control (the percentage of patients with examinations and measurements performed according to the guidelines), and (2) outcome control (the percentage of patients who achieved target values: HbA1c <7.0%, blood pressure <150/85 mmHg, total cholesterol <5 mmol/l). Based on available data, expressing the number of patients known to have achieved target values as a percentage of the total target population results in a quality indicator (3) that combines process and outcome control. The feasibility of the interventions was evaluated based on the participation rates of the patients and the GPs and patient and provider satisfaction.

Analysis

Statistical analyses were performed using SPSS for Windows. For baseline cross-sectional analyses we used Student's T-test, and the One-way Anova for variables with a normal distribution, Mann-Whitney-U test for non-normal variables, and the χ^2 test for categorical variables. For longitudinal analyses we performed an 'intention-to-treat analysis' and used the McNemar method. The different groups were not directly compared with each other because of the possible bias resulting from the non-randomised design.

RESULTS

The prevalence of diabetes in the study area was representative for a larger area, and the size of the practice population and the percentage of GPs working in solo-practices were similarly representative for the population of the Netherlands. None of the GPs discontinued their participation in the study.

Among the 2660 patients with type 2 diabetes treated in the primary care setting (*figure 1*), 174 (6.5%) were excluded by their GPs for reasons of terminal illness or dementia. Altogether, 2486 patients were eligible for the study: 1244 were assigned to intervention group A, 842 to group B, and 400 to the standard care group.

Baseline data are shown in *table 1*. The three groups differed significantly at baseline with respect to age, diabetes duration, glycaemic control, cardiovascular risk factors, and treatment. Patients who were excluded were older (77.3 *vs* 68.4 years), had more cerebrovascular complications (23 *vs* 11%), used significantly less antidiabetic, antihypertensive, and lipid-lowering medication, and had their eyes (26 *vs* 55%) and feet (22 *vs* 36%) examined less frequently compared with participants.

Out of 2486 patients, 2048 (82%) were available for follow-up after two years: 217 (8.7%) patients died, 154 (6.2%) were referred to an internist, 66 (2.7%) moved, and two patients were lost to follow-up. The referral percentages to secondary care were 7% for group A, 4% for B, and 9% for the standard care group. The follow-up for the different groups was 77% for intervention A, 88% for intervention B and 79% for the standard care group. In intervention A, 1121 (90.1%) of patients responded to the invitation for a consultation with the DSN at least twice during the three years of the project, and 33 (2.7%) were excluded by the GP after initially participating.

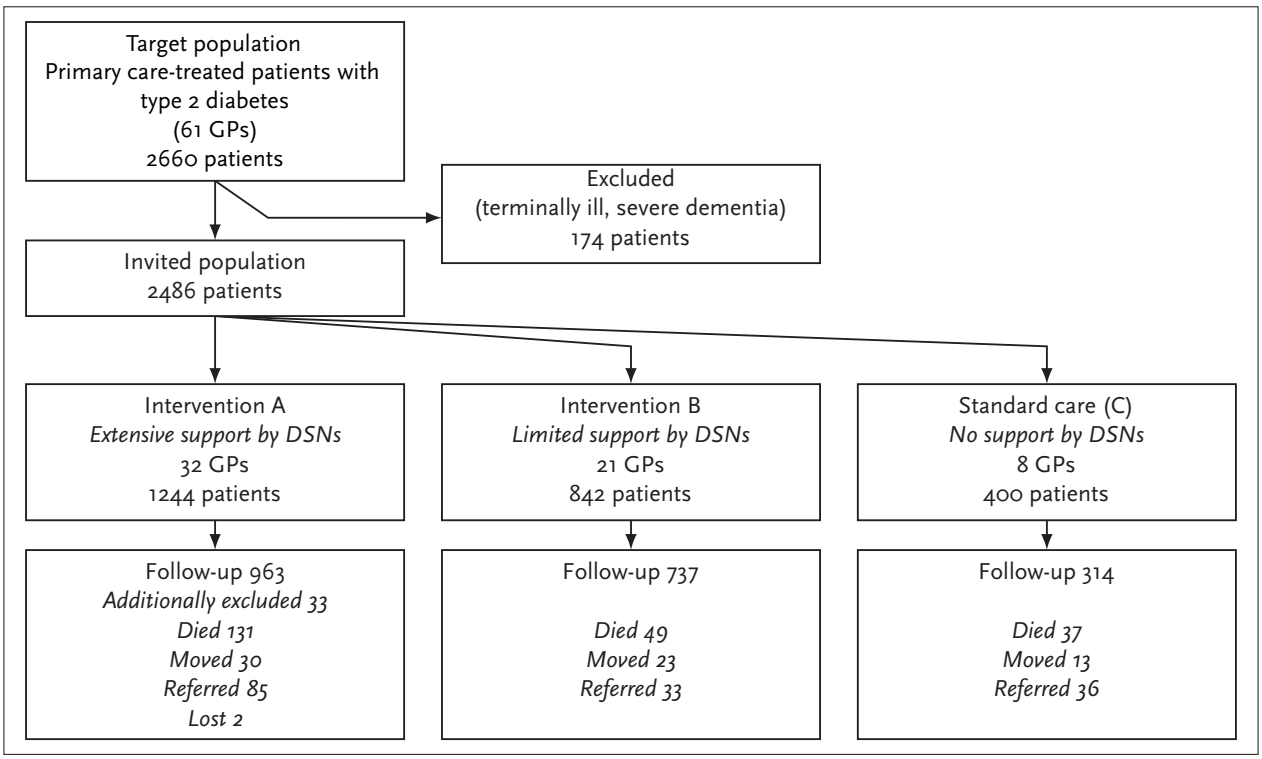

Figure 1

Selection of patients with type 2 diabetes treated in primary care, assignment to the interventions in the ZODIAC study, and follow-up between 1998 and 2001

Table 1

Baseline data from patients with type 2 diabetes treated in primary care in intervention groups A and B, and standard care group C (means or percentages), 1998/1999

	INTERVENTION GROUP		STANDARD CARE		
	A	B	C	TOTAL	P VALUE*
Practice characteristics					
Gender GPs male (%)	88	85	100	89	0.52
Practice size	2612	2523	2732	2598	0.51
Prevalence DM (%)	1.9	2.3	2.4	2.1	0.09
Patients (N)	1127	842	400	2369	
Gender female (%)	58	54	60	57	0.07
Age (years)	68.7	67.3	70.3	68,5	<0.001
Diabetes duration (years)	7.7	6.7	6.5	7.2	0.002
HbA_{1c} (%)	7.5	7.3	7.3	7.4	0.01
BMI (kg/m^2)	28.9	28.0	26.7	28.8	0.01
Systolic blood pressure(mmHg)	155	150	152	153	<0.001
Diastolic blood pressure (mmHg)	84	83	84	84	0.15
Total cholesterol (mmol/l)	5.7	5.5	5.9	5.7	0.003
Total cholesterol/HDL ratio	5.3	5.2	5.0	5.2	0.25
Diabetes treatment					
Diet (%)	13	20	10	15	<0.001
Oral agent (%)	70	64	75	69	
Insulin (%)	14	12	12	13	
Insulin and oral agent (%)	2	5	3	3	

**Single test for statistically significant differences between A, B, and C.*

The opportunity to consult with a DSN on-demand was not frequently used. The reasons for these consultations were, in the majority of cases, for support with respect to education and instruction of insulin therapy within the primary care setting: 27/47 (57%) for group A and 11/19 (58%) for group B.

The effects of the interventions are shown in *tables 2* and *3*. *Table 2* shows the change in process control. Performance significantly improved with respect to process parameters for both interventions A (extensive support by DSNs) and B (limited support by DSNs): at two-year follow-up, all examinations and measurements were performed more frequently for group A, and most for B. In intervention A, where the DSN is responsible for the annual check-up, the performance was very high, ranging from 84 to 90%; for intervention B this ranged from 18 to 85%. In the standard care group, the performance regarding process parameters remained stable or decreased, ranging from 2 to 72% for the various parameters after two years of follow-up. *Table 3* shows the change in outcome control:

Table 2

Performance with respect to process control in the treatment of patients with type 2 diabetes treated in primary care in intervention groups A and B, and standard care group C in 1998/1999 and 2000/2001

		BASELINE (%)	FOLLOW-UP (%)	P VALUE	DIRECTION OF SIGNIFICANT CHANGE
Foot examination	A	44	87	<0.001	↑
	B	31	41	<0.001	↑
	C	16	11	0.11	-
Eye examination	A	48	84	<0.001	↑
	B	57	67	<0.001	↑
	C	41	53	0.001	↑
HbA_{1c}	A	57	89	<0.001	↑
	B	67	75	<0.001	↑
	C	62	63	0.91	-
Blood pressure	A	76	88	<0.001	↑
	B	89	85	0.03	↓
	C	78	72	0.03	↓
Total cholesterol	A	46	89	<0.001	↑
	B	59	63	0.06	-
	C	48	39	0.008	↓
Creatinine	A	54	89	<0.001	↑
	B	63	74	<0.001	↑
	C	60	63	0.33	-
Body mass index	A	0.3	88	<0.001	↑
	B	0.3	18	<0.001	↑
	C	0.6	2	0.45	-
Smoking status known	A	5	90	<0.001	↑
	B	25	41	0.001	↑
	C	7	11	0.001	↑

Table 3

Quality indicators for the treatment of patients with type 2 diabetes treated in primary care in intervention groups A and B, and standard care group C in 1998/1999 and 2000/2001

		PROCESS CONTROL	OUTCOME CONTROL				PROCESS AND OUTCOME CONTROL COMBINED
	GROUP	(%)	BASELINE (%)	FOLLOW-UP (%)	P VALUE	DIRECTION OF CHANGE[#]	(%)[*]
HbA_{1c} ≤7.0%	A	89	43	42	0.76	-	37 (350/963)
	B	75	46	48	1.0	-	36 (264/737)
	C	63	50	42	0.03	↓	27 (84/314)
Blood pressure ≤150/85 mmHg	A	88	40	52	<0.001	↑	46 (439/963)
	B	85	47	51	0.02	↑	44 (321/737)
	C	72	43	42	0.92	-	30 (95/314)
Total cholesterol ≤5 mmol/l	A	89	28	40	<0.001	↑	35 (341/963)
	B	63	33	49	<0.001	↑	31 (227/737)
	C	39	26	26	0.27	-	10 (32/314)

[*]*Known achieved target values in the total population (%);* [#]*p<0.05.*

performance regarding the percentage of patients who achieved target values for the different groups. The percentage of patients with good glycaemic regulation remained stable in intervention groups A and B, and decreased in the standard care group. For both blood pressure and hypercholesterolaemia, outcome control improved in intervention groups A and B, while there was no change in the standard care group. Based on the available data, expressing the number of patients known to have achieved target values as a percentage of the total target population results in a quality indicator that combines process and outcome control. It appears that the performance for this quality indicator was 35 to 46% for intervention A, 31 to 44% for intervention B, and 10 to 30% for the standard care group.

The GPs rated the project as good in 70 and 69% of cases and adequate in 30 and 25% of cases in interventions A and B, respectively; the patients were satisfied in 81% of cases according to their GPs. There was no mention of dissatisfaction.

DISCUSSION

In this study, examining two interventions with structured shared care and task delegation, which was targeted at an unselected group of patients with type 2 diabetes treated in a primary care setting, we found improvements in process and outcome control. Performance for process parameters increased for both interventions, as did the percentage of achieved target values on the individual patient level for blood pressure and total cholesterol, but not for blood glucose control. In contrast, the standard care group showed minimal improvements, and even some deterioration. The patient participation rate remained high throughout the study, and none of the GPs discontinued participation.

Strengths and limitations

A strong point of this study is that the results may, for the most part, be generalised to similar patient populations. We studied a highly unselected patient population, unlike many of the previous studies on this topic. The quality of care improved even though changes are difficult to effect in busy primary care environments.[20] The interventions used in this study may be used in other primary care settings, provided the same exclusion criteria are applied. Excluding those terminally ill or having dementia seems realistic from a clinical point of view: intensive therapy is either not useful for prevention of long-term complications or not possible.[21]

A limitation of our study is the nonrandomised design. To study how evidence and guidelines may be translated into daily practice, flexibility is necessary to deal with pragmatic issues; rigorous nonrandomised study designs including quasi-experimental, time series and observational studies are sometimes more appropriate.[22] We chose, for pragmatic reasons, to assign the patients to the intervention groups according to the preferences of the GP working groups. The effects of the interventions may have been overestimated as a consequence of the design,[23] and baseline values were not comparable for the three groups analysed. Direct comparison would consequently be difficult to interpret. We therefore decided to limit our analysis to independent descriptions of the three intervention groups, and focussed on the quality indicators at the individual patient level instead of on group means. At the same time, there was a difference in the amount of available data: in group A the data collected during consultations with the patients by the DSNs were nearly complete. In groups B and C, however, the data were collected from the GPs' patient records, where the availability of data was not optimal. Obtaining data provided from medical records can lead to underreporting of care delivered.[24] However, although the same lack of documentation has been found by others,[20,25] and intermediate outcomes may not be different for the patients concerned,[25] the negligent recording of risk factors reflects suboptimal care, because opportunities to detect increased risk and therefore to start treatment are missed. Moreover, the quality of care delivered lacks transparency.

Comparison with other studies

With intervention A (extensive support by DSNs) a large increase was found with respect to process control, with an overall high performance rate between 84 and 90%, which is higher than that found in another recent study (41 to 80%).[25] This appears to be a direct effect of the central role of the DSNs who were responsible for performing the annual check-up. For intervention B (limited support by DSNs), process control improved as well, and was comparable with, or higher than (but still suboptimal) the findings reported by Goudswaard *et al.*[25] The standard care group showed few improvements, and even some deterioration. Renders *et al.* reported a similar finding for their reference group.[26]

For outcome control (achieved target values), in both intervention groups the percentage of patients achieving target values increased for blood pressure regulation and lipid control. Although difficult to compare, other intervention studies with a central role for DSNs showed improvement in blood pressure and/or lipid profile as well,[27-29] whereas programmes without a central role for DSNs found no (significant) positive effect on these outcomes.[26,30] In the standard care group no changes in outcome control for blood pressure or hypercholesterolaemia were found.

In the intervention groups we did not find an increase in the percentage of patients with good glycaemic regulation, whereas other intervention programmes did.[27,29-32] The percentage of patients with an HbA_{1c} <7 is comparable or somewhat lower compared with that found by others.[26,30,32] An explanation for the lack of improvement may be that the baseline HbA_{1c} was already quite acceptable in this unselected population, which may have left little room for improvement (ceiling effect).[33] The GPs in all three participating groups treat a higher percentage (80%) of the total diabetic population in primary care than in most other programmes (61 to 75%),[26,34,35] probably also including a higher percentage of patients who are difficult to treat. Since metabolic control tends to deteriorate with the duration of the disease,[36] keeping glycaemic control stable could be seen as a positive effect of the interventions. In the standard care group, the percentage of patients with good glycaemic regulation decreased, which was also reported by De Sonnaville *et al.* for their control group.[30] Using a quality indicator that combines process and outcome control may be a simple and transparent method to indicate the quality of care delivered, enabling benchmarking of performance at the level of the individual health care providers or teams.

In intervention group A, 9.9% of patients did not visit the DSN in either one of the three project years. This percentage seems acceptable as it is within the variance (0 to 17%) that is mentioned in a Dutch literature study into diabetes patients not showing up within a period of 6 to 13 months.[37] Reasons mentioned by patients varied between 'just don't want to' and 'long-term admittance to the hospital' or 'partner to ill' or 'family problems'. Many patients who could not participate in one year resumed participation in the next year.

The follow-up period may have been too short to show all the potential positive effects, since the GPs only started to make more use of on-demand consultations after two years. We expect that the intervention groups and the standard care group will diverge further with respect to the quality of care as, in intervention group A, the recommendations from the internists become increasingly stringent and extensive at the GPs' request. Moreover, we are currently seeing a large annual increase in on-demand consultations in intervention groups A and B.

Implications

Abnormal but unrecorded values deprive the GP of possible indications for starting or adjusting treatment, and may therefore hamper the achievement of optimal diabetes care at the individual patient level. Moreover, unrecorded values limit the transparency of the care delivered. In other healthcare settings, quality indicators have yet to be included in the assessment of the quality of diabetes care.[38] Although there have been proposals,[39,40] in the Netherlands there is not yet an official set of quality indicators, while this would be useful for benchmarking and to compare effect evaluations of interventions to improve the quality of diabetes care.

The delegation of tasks to nurses appears to improve process control, as process indicators improved and reached high levels when nurses were responsible for performing the annual check-ups. Concomitantly, outcome control appears to improve at the level of individually reached target values.

Ultimate proof of the effectiveness of these interventions can only be seen after analysing the development of complications as was done recently by Gaede *et al.*[41] The ZODIAC study has now entered its seventh year which will make the assessment of long-term effects of the presented interventions possible within the next few years.

ACKNOWLEDGEMENTS

We thank all the GPs, their assistants and the nurses specialised in diabetes who participated in the ZODIAC study for helping to collect the data. This research was made possible financially by the Research Fund Internal Medicine Zwolle, Care Foundation and Health Care Research Foundation, the Netherlands.

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